

BARNES & THORNBURG LLP

11 South Meridian Street
Indianapolis, Indiana 46204
(317) 236-1313
(317) 231-7433 Fax

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

<i>Group:</i>	1651	}	
<i>Confirmation No.:</i>	7977	}	
<i>Application No.:</i>	10/634,292	}	Filed Electronically on
<i>Invention:</i>	Nano-Structured Polymers For Use As Implants	}	February 18, 2009
<i>Applicant:</i>	Haberstroh et al.	}	
<i>Filed:</i>	August 5, 2003	}	
<i>Attorney Docket:</i>	3220-73239	}	
<i>Examiner:</i>	Susan Marie Hanley	}	

SUPPLEMENTAL RESPONSE UNDER 37 C.F.R. § 1.111

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

On November 6, 2008 applicants submitted an amendment and response to the Office Action mailed August 20, 2008. Since filing that response, Applicants became aware of a further prior art reference that served as the basis for rejecting related subject matter in co-pending application no. 10/362,148. Accordingly, applicants submit herewith a Supplemental Information Disclosure Statement citing the new reference, US Patent No. 6,805,898.

No further amendments to the claims are submitted with this supplemental response as applicants believe the claim as amended in the response filed on November 6, 2008 are patentable over the prior art teachings.

As noted in the response submitted on November 6, 2008, applicants respectfully submit that one of ordinary skill in the art would readily appreciate that different materials (e.g., ceramics vs. polymeric materials) behave very differently upon implantation into an

animal. Thus while ceramic and polymeric materials have each been commonly used as implant materials, one of ordinary skill in the art would not think of the two materials as being equivalents. One of ordinary skill simply would not have any reasonable expectation that results reported with regards to an implantable ceramic material (e.g., the results reported in US Patent no. 6,270,347) would necessarily be applicable to implantable polymeric materials, and vice versa. Accordingly, one of ordinary skill in the art would not have a reasonable expectation that the results reported in the '347 patent with regards to the use of nanostructured ceramics for orthopaedic/dental applications would be relevant with regards to different materials, including polymeric materials (i.e., the '347 teaching is limited to nano-sized ceramic materials and composites thereof, and provides no motivation for the preparation of compositions that comprise a polymeric material wherein the polymeric material itself displays nano-sized surface features).

Furthermore, the presently claimed invention is directed to a nano-structured synthetic implant comprising a polymeric material, wherein the polymeric material displays nano-sized surface features having a 25 nm to less than 100 nm dimension. The prior art for all their combined teachings simply fail to teach or suggest that a polymer surface could be modified to display nano-sized surface structures having a size less than 100 nm, or that surface features having a dimension of less than 100 nm would produce the unexpected properties described in the present specification. The results obtained by applicants use of polymeric materials that were prepared to display nano-sized surface features (e.g., protrusions and grooves) that have a dimension of 25 nm to less than 100 nm were surprising even in light of the previous reported results disclosed in the '347 patent. Such unexpected results are the hallmark of non-obviousness.

As disclosed on page 4, lines 23-27, page 11, lines 19-33 and Examples 12-14, applicants discovered that polymeric materials displaying nanometer features had superior properties as cell substrates. More particularly, surface features of less than 100 nm (i.e. nanometer range) showed surprising superiority to micron (i.e., 5 μ m to 10 μ m) textured surfaces in terms of cell adhesion and proliferation (see Declaration Under 37 CFR 1.132 previously submitted on January 29, 2008 and the Declaration Under 37 CFR 1.132 accompanying this submission). Accordingly, applicants have found that preparing polymer surface features having dimensions below 100 nm produces significant and surprising results. The prior art fails to teach or suggest that any benefit could be derived from preparing compositions having surface features with dimensions of less than 100 nm.

The mere fact that references can be combined or modified does not render the resultant combination [or modification] obvious unless the results would have been predictable to one of ordinary skill in the art. *KSR International Co. v. Teleflex Inc.*, 550 U.S. ___, ___, 82 USPQ2d 1385, 1396 (2007). Applicants respectfully submit the properties exhibited by the claimed compositions were not predictable based on the prior art teachings at the time of the present invention. Accordingly, the cited prior art for all its combined teaching fails to teach or suggest the present application.

Applicants are the first to disclose a composition comprising a polymeric material, wherein the polymeric material itself displays nano-sized surface features having at least one dimension that is less than 100 nm. Furthermore, applicants have discovered that polymeric material that displays surface features having a dimension less than 100 nm exhibit surprising beneficial properties for enhancing cell adhesion and cell proliferation. The prior art fails to teach or suggest applicants unique polymeric material and fails to provide any motivation to do what applicants have done and now claim as their invention.

Applicants respectfully submit that the claimed invention is patentably distinct over the teachings of the Webster '347 patent, and applicants respectfully request the withdrawal of the rejection based on 35 USC 103(a) and passage of the application to allowance. If any further discussion of this matter would speed prosecution of this application, the Examiner is invited to call the undersigned at (434) 220-2866.

Respectfully submitted,



John P. Breen
Registration No. 38,833
Attorney for Applicants

(317) 261-7940
Indianapolis, Indiana 46204